

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov>)

Components of Participating Organizations

Office of Behavioral and Social Sciences Research (OBSSR), (<http://obssr.od.nih.gov>)

National Cancer Institute (NCI), (<http://www.nci.nih.gov>)

National Center for Complementary and Alternative Medicine (NCCAM), (<http://www.nccam.nih.gov>)

National Heart, Lung, and Blood Institute (NHLBI), (<http://www.nhlbi.nih.gov>)

National Human Genome Research Institute (NHGRI), (<http://www.genome.gov>)

National Institute of Child Health and Human Development (NICHD), (<http://www.nichd.nih.gov>)

National Institute of Dental and Craniofacial Research (NIDCR), (<http://www.nidcr.nih.gov>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (<http://www.niddk.nih.gov>)

National Institute of Environmental Health Sciences (NIEHS), (<http://www.niehs.nih.gov>)

National Institute of Mental Health (NIMH), (<http://www.nimh.nih.gov>)

National Institute of Nursing Research (NINR), (<http://ninr.nih.gov/ninr/>)

National Institute on Aging (NIA), (<http://www.nia.nih.gov>)

National Institute on Alcohol Abuse and Alcoholism (NIAAA), (<http://www.niaaa.nih.gov>)

National Institute on Arthritis, Musculoskeletal, and Skin Diseases (NIAMS), (<http://www.niams.nih.gov>)

National Institute on Drug Abuse (NIDA), (<http://www.nida.nih.gov>)

National Institute on Deafness and Other Communications Disorders (NIDCD), (<http://www.nidcd.nih.gov>)

Title: Social and Cultural Dimensions of Health

Announcement Type

This is a reissuance of [PA-02-043](#), which was previously released on December 21, 2001.

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Key Dates

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Letter of Intent Receipt Date(s): Not applicable

Application Receipt Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Peer Review Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Council Review Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Earliest Anticipated Start Date: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

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Due Dates for E.O. 12372

Not applicable.

Additional Overview Content

Executive Summary

- The ultimate goal of this program announcement is to encourage the development of health research that integrates knowledge from the biomedical and social sciences.

- This announcement invites applications to (a) elucidate basic social and cultural constructs and processes used in health research, (b) clarify social and cultural factors in the etiology and consequences of health and illness, (c) link basic research to practice for improving prevention, treatment, health services, and dissemination, and (d) explore ethical issues in social and cultural research related to health.
- This program announcement is a re-issuance and revision of PA-02-043.
- The total amount to be awarded depends on the scientific merit of applications and the funds available at the participating NIH Institutes/Centers.
- The anticipated number of awards is contingent on their scientific merit and the funds available in the general funding pool of the participating NIH Institutes/Centers.
- The type of mechanism is the Research (R01) Award. NIH Institutes and Centers may also accept applications for other mechanisms.
- Eligible organizations include for-profit and not-for-profit, public or private organizations, units of state and local governments, eligible agencies of the Federal Government, domestic or foreign institutions/organizations, faith-based or community-based organizations, and Native American tribal organizations.
- Eligible principal investigators are any individuals with the skills, knowledge, and resources necessary to carry out the proposed research.
- The number of different applications each applicant may submit is unrestricted.
- The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, E-mail: GrantsInfo@nih.gov.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The ultimate goal of this program announcement is to encourage the development of health research that integrates knowledge from the biomedical and social sciences. This involves the further development of health-related social science research relevant to the missions of the NIH Institutes and Centers (ICs) and the development of multi- or inter-disciplinary research that blends the theories and approaches of the social and biomedical sciences. Within the broad spectrum of research identified in this announcement, applicants are encouraged (but are not required) to employ multiple (i.e., biological, behavioral, and/or social) levels of analysis.

This announcement invites applications to (a) elucidate basic social and cultural constructs and processes used in health research, (b) clarify social and cultural factors in the etiology and consequences of health and illness, (c) link basic research to practice for improving prevention, treatment, health services, and dissemination, and (d) explore ethical issues in social and cultural research related to health.

This program announcement is a re-issuance and revision of PA-02-043 and is based upon recommendations submitted to the NIH in conjunction with the conference entitled *Toward Higher Levels of Analysis: Progress and Promise in Research on Social and Cultural Dimensions of Health*, June 27-28, 2000, Bethesda, MD. For a summary of the conference, see http://obssr.od.nih.gov/Conf_Wkshp/higherlevel/conference.html. Also see "Social Science and Health Research: Growth at the NIH," American Journal of Public Health, 94, 1, Jan. 2004: 22-28 (http://obssr.od.nih.gov/Publications/ajph_socsci_nih.pdf). You may request these publications from the Office of Behavioral and Social Sciences Research, Office of the Director, National Institutes of Health, Bethesda, MD 20892.

Social scientists have made significant strides in shedding light on the basic social and cultural structures and processes that influence health. Social and cultural factors influence health by affecting exposure and vulnerability to disease, risk-taking behaviors, the effectiveness of health promotion efforts, and access to, availability of, and quality of health care. Social and cultural factors also play a role in shaping perceptions of and responses to health problems and the impact of poor health on individuals' lives and well-being. In addition, such factors contribute to understanding societal and population processes such as current and changing rates of morbidity, survival, and mortality.

Numerous reports from the Institute of Medicine and National Research Council have pointed to the importance of social and cultural factors for health and the opportunities for improving health through a better understanding of mechanisms linking the social and cultural environment to specific health outcomes. To realize these opportunities, social science research related to health must be further developed and ultimately integrated into interdisciplinary, multi-level studies of health. Linking research from the macro-societal levels, through behavioral and psychological levels, to the biology of disease will provide the integrative health research necessary to fully understand health and illness.

This program announcement invites applications for research on the social and cultural dimensions of health in five areas:

1. Basic social and cultural constructs and processes used in health research.
2. Etiology of health and illness
3. Consequences of poor health for individuals and social groups.
4. Linking science to practice to improve prevention, treatment, health services, and dissemination.
5. Ethical issues in social and cultural research.

The goal of this announcement is to encourage further development of health-related social sciences research relevant to the missions of the ICs. These missions encompass a broad range of scientific questions related to the health and well-being of our nation's people. Information about the specific missions of the ICs participating in this program announcement is posted at <http://www.nih.gov/icd/>.

1. Basic Constructs and Processes

Advances in social science research on health depend on a foundation of basic theory and knowledge that describes social structures, the dynamics of social and cultural processes, and the ways in which individuals are located in and interact with the environment, social structures, and cultural factors. Several key sociodemographic constructs, including race, ethnicity, gender, age, and socioeconomic status, are widely used in studies of the etiology of health and disease and in research that describes and monitors the distribution of disease across social categories, geographic areas, and time. However, the meanings of such constructs depend on their cultural, geographical, and historical context, and their utility in health research depends on their use in ways that are theoretically and historically grounded. In addition, the concept of *culture* requires careful theoretical grounding in health studies. Most social scientists agree that the concept of culture is complex and implies a dynamic and ever-changing process.

This program announcement encourages research on basic social and cultural constructs and processes in the following areas:

Social Stratification and Inequalities

Research is needed to explore the implications of different conceptualizations and measurements of social stratification systems and processes, such as socioeconomic status (SES) and social class, age, gender, and race/ethnicity for understanding health at the individual and higher levels of aggregation (e.g., community). Research to improve the monitoring and understanding of inequalities in health and disease among diverse groups, and the implications for monitoring of strategies used to measure basic constructs such as socioeconomic status and social class, age, gender, race, and ethnicity.

The National Research Council's study of *Critical Perspectives on Racial and Ethnic Differences in Health and Late Life* discusses several issues related to racial and ethnic inequalities in health, including the nature of racial and ethnic differences, an outline of causal pathways implicated in health disparities, and a research agenda in the field of racial and ethnic differences in health. (See N. B. Anderson, R. A. Bulatao, and B. Cohen, Editors, Panel on Race, Ethnicity, and Health in Later Life, National Research Council, [*Critical Perspectives on Racial and Ethnic Differences in Health in Late Life*](#), The National Academies Press, Washington, DC, 2004.)

Social Integration

Research is required to clarify the social, cultural, and economic factors that influence the social integration of individuals and the social cohesion of groups, including the causal dynamics of social networks.

Culture

Studies are necessary to improve the conceptualization and operationalization of culture as well as of social and cultural change in health research. Efforts are needed to identify those definitions and dimensions of cultural phenomena and intra-cultural and inter-cultural variation and change that are most useful in understanding health, and the mechanisms through which cultural phenomena influence health.

2. Etiology

Social science research on the etiology of health and illness recognizes that health may be affected by a diverse set of mechanisms operating among and within social structures existing at different levels. At the highest levels are structures and processes that involve and affect populations broadly: government, media, economic systems, social stratification, political processes and policy-making, and broadly-held cultural values and practices. Some of these processes also operate in communities and neighborhoods, in social institutions (e.g., schools, churches, and businesses), and in social or professional organizations. However, at these levels processes contributing to social cohesion, social support, social control, social and cultural conflict, and the development and enforcement of social and cultural norms play a larger role. In families and small groups, interpersonal processes such as conflict and support, socialization, and sharing of resources play a dominant role.

A valuable contribution of the social sciences is to understand health and disease not solely as an individual biological problem, but as a social phenomenon associated with social ties and other forms of social influences. From this perspective, research must address how mechanisms that link social and cultural phenomena to health operate within and emerge from specific social contexts. Social contexts provide the stage for social and cultural factors to influence health, and the characteristics of social context directly affect social and cultural processes.

This Program announcement encourages research on topics and questions such as the following:

Overarching Issues

Research is needed to improve understanding of how macro-level (societal) factors, such as social policies, structures, and cultural norms, are linked to micro-level (individual) factors, such as a person's behaviors, and ultimately to health. What are the causal pathways that lead from the sociocultural environment to general vulnerability to disease and disease-specific outcomes? Research that integrates theories and methods from the social and biomedical sciences is particularly encouraged to address these questions.

Interpersonal, Social, and Cultural Factors

Essential are studies of the implications for health of the characteristics and content of network ties and of how individuals and groups organize themselves into networks and other social arrangements, including the mechanisms through which social integration/cohesion, social influence, and other social processes affect the health of individuals and contribute to health disparities. More research is needed on cultural processes and belief systems (such as religion or the nature of health/disease), at the individual, family, community, and institutional levels, and their relationships to health, including recovery from disease and addiction, with particular attention to potential mediating mechanisms (e.g., socially-determined patterns of stress and coping with stress).

Social Contexts

Research is considered necessary on the role of social contexts (e.g., family and households, religious institutions, work places, schools, health-care organizations and systems, neighborhoods, and communities, geographic location, residential segregation, legal and administrative policies, communication environments) in mediating or moderating sociocultural influences on health of individuals. Studies are required to conceptualize and measure social contexts in order to specify which particular aspects of social context are relevant to health and the mechanisms through which they operate. This includes research on how health policies impact on diverse populations, such as those defined by immigration status, gender, race/ethnicity, sexual orientation, or age, and on the pathways through which social policies (such as gun control, urban renewal, welfare reform, and taxes on alcohol and tobacco products) affect the health of diverse populations.

3. Consequences of Poor Health

Connections among health, functional capacity, and productivity are complex and difficult to disentangle, but empirical research is emerging that addresses the consequences of poor health for economic well-being at the individual, family, and population levels. Understanding the consequences of health and illness is important to the mission of the NIH. First, health disparities among groups varying in socioeconomic status result in part from the reciprocal influence of SES on health and health on SES. The nature of these feedbacks needs to be fully understood if we are to understand the mechanisms underlying health disparities. Second, the value of investment in improving health can be only partially understood by focusing on health outcomes alone. For example, improvements in quality of life resulting from social, economic, and cultural change at both the individual and societal level are an important part of the picture.

This program announcement encourages research on the consequences of poor health, such as the following:

Self Care

Research is desired on self-care or self-regulation (including the choice of complementary or alternative medical practices) as a response to illness and in the management of health conditions, considering the influence of social, cultural, and economic factors on the adoption and consequences of this strategy.

Coping Strategies

Required are investigations of the coping strategies people use to adapt to illness and disability, the influence of social, cultural, and economic factors on these strategies, and the impact of these strategies on health and well-being at the individual, family, and community level. Research on the consequences of death and dying for the health and well-being of the deceased's relatives and friends as well as on the coping strategies people use to adapt to illness, disability, and death of a relative or close friend.

Social Stigma

Needed are studies of stigma across physical and mental health conditions (including addictions), care settings, outcomes and groups, including research on the social and cultural origins of stigmatization of illnesses. What are the implications of stigma for access to care and treatment? How does stigma affect outcomes across health conditions?

Impact of Health on Society

Research is necessary to examine how the health of individuals impacts upon macro-level processes and systems is also needed. How does the health of individual members of a group (e.g., family, household, firm) affect the composition and functioning of the group? Also of interest is research on the influence of poor health on economic performance of organizations and societies. (For example, see International Studies of Health and Economic Development, NIH Guide to Grants and Contracts, May 30, 2000; <http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-01-001.html>)

4. Linking Science to Practice to Improve Prevention, Treatment, Health Services, and Dissemination

The social sciences are important in efforts to prevent and treat illness and to promote health. Research in the social sciences can pinpoint environmental contexts, social relationships, interpersonal processes, and cultural factors that lead people to engage in healthy behaviors, seek health services before disease symptoms worsen, and participate with medical professionals in treating illness. The incorporation of social science research and theory into prevention, treatment, service, and health-promotion programs is likely to result in more effective interventions. In addition, research on the dissemination and translation of social science research findings can ensure that investments in basic research have their maximum impact on health.

This program announcement encourages social sciences research on prevention, treatment, health services, health promotion, and information and program dissemination in the following areas:

Prevention

Greater theoretical development and conceptual work is needed in the field of prevention, including clarifying the concepts of risk and protection and their meanings within distinct populations, defining the distinctions between health promotion and disease prevention, and promoting generalizability of theoretical frameworks. Research is desirable to design, implement, and evaluate interventions based upon the theories, concepts, and methods identified earlier in this announcement (e.g., social networks, social contexts, cultural beliefs).

Treatment and Management of Disease

Research is needed on cultural competence at multiple levels, including health systems, agencies and providers, with an emphasis on primary care and mental health settings. Also, research is essential to define what constitutes "culturally competent care", develop and test different models (best practices) of culturally competent care, and test models in randomized controlled trials. Research is desired that explores the interface between traditional/alternative and allopathic/western medicine and health maintenance practices and identifies the circumstances under which either or both function more effectively.

Services

Research on the development, dissemination, and accessibility of new therapies, technologies and services, such as retrovirals and anti-psychotics. How do social and cultural factors affect these processes and what impact do they have on services and treatment? How do social, cultural, economic, and policy mechanisms influence equitable access to health care and the quality of care received?

Dissemination and Adoption

Research is essential on the processes through which social and behavioral interventions are incorporated into general practice. What accounts for success or failure (i.e., adoption vs. non-adoption)? How does this differ from the adoption of biomedical treatments and interventions? Systematic research is required on methods to increase the adoption of tested and effective preventive interventions, treatment models, and service delivery strategies. Also increased research is needed that will allow rigorous comparisons of the effects of alternative methods of diffusion and dissemination.

5. Ethical Issues in Social and Cultural Research

The development of new and more complex research methods in the social sciences, combined with dramatic advances in computing power, complicates standard ethical concerns of confidentiality, privacy, and consent. Higher levels of analysis imply analysis of data at the group, institution, or community level, raising the prospects of consent at these levels and how such consent might be obtained. Sensitivity exists not only at the individual level but also for the groups and institutions with which individuals affiliate.

This program announcement encourages social sciences research on ethical issues in the following areas:

Ethical issues arising from research that links the individual to groups, organizations, neighborhoods or communities.

Threats to confidentiality of data collected in multi-level studies by advancing statistical methods for masking or altering individual data and studying how such procedures impinge on the ability to conduct valid analyses.

Unintended consequences of research aimed at understanding variation among individuals and among groups. How to avoid overemphasizing individual and group differences and thereby reinforcing existing patterns of stratification in health care or other areas.

Community consultation in research projects involving identified population groups. How can individual informed consent best be accomplished in this setting?

Section II. Award Information

1. Mechanism of Support

This funding opportunity will use the NIH Research (R01) award mechanism. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses just-in-time concepts. It also uses the modular as well as the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format described in the PHS 398 application instructions. Otherwise follow the instructions for non-modular research grant applications.

2. Funds Available

Applications received in response to this program announcement will compete for funds in the general funding pool of the participating NIH ICs. No specific funds have been set aside for this announcement. The number and size of the awards will depend on the number of applications received, their relative scientific merit, and the general availability of funds for investigator-initiated research at the participating ICs.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary.

Section III. Eligibility Information

This section addresses considerations or factors that make an applicant or application eligible or ineligible for consideration. Applicants' failure to meet an eligibility criterion by the time of an application deadline will result in the return of the application

without review. Applications for renewal or supplementation of existing projects are eligible to compete with applications for new awards.

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State governments
- Units of local governments
- Eligible agencies of the Federal government
- Foreign institutions
- Domestic institutions
- Faith-based or community-based organizations

Applications from foreign institutions must conform to the NIH's policy for foreign grants. See http://grants.nih.gov/grants/policy/nihgps/part_iii_5.htm.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

2. Cost Sharing or Matching

Not applicable.

3. Other-Special Eligibility Criteria

Not applicable.

Section IV. Application Submission Instructions

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, E-mail: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application instructions and forms. Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates and Times

Applications must be mailed on or before the receipt date described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>. Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Applications will be reviewed and awards will be made according to the standard schedule described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>.

Letter of Intent Receipt Date(s): Not applicable

Application Receipt Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Peer Review Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Council Review Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

Earliest Anticipated Start Date: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

3.A.1. Letter of Intent

A letter of intent is not required for this funding opportunity.

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

3.C. Application Processing

Applications must be submitted on or before the application receipt dates described above ([Section IV.3.A.](#)) and at <http://grants.nih.gov/grants/dates.htm>.

The NIH will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm> (See also [Section VI.3. Reporting](#))

6. Other Submission Requirements

Specific Instructions for Modular Grant applications

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular budget format. The modular budget format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular budgets. Additional information on modular budgets is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

Specific Instructions for Applications Requesting \$500,000 (direct costs) or More per Year.

Applicants requesting \$500,000 or more in direct costs for any year must carry out the following steps:

- 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;
- 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,
- 3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

Plan for Sharing Research Data

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy. (http://grants.nih.gov/grants/policy/data_sharing).

The reviewers may assess the reasonableness of the data sharing plan or the rationale for not sharing research. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131. Investigators responding to this funding opportunity should include a **plan** for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report. (PHS 2590). See [Section VI.3. Reporting](#).

Section V. Application Review Information

1. Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

Applications will be evaluated according to the standard criteria for scientific merit. Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established PHS referral guidelines. Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- Receive a written critique
- Receive a second level of review by the appropriate national advisory council or board.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

Data Sharing Plan: The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

2.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofr and http://ott.od.nih.gov/newpages/rtguide_final.html). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the Principal Investigator before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report. (PHS 2590). See [Section VI.3. Reporting](#).

3. Anticipated Announcement and Award Dates

Not applicable.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_part4.htm.

A formal notification in the form of a Notice of award will be provided to the applicant organization. The notice of award signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA (Notice of Grant Award) are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See also [Section IV.5 Funding Restrictions](#).

NGAs are sent via e-mail to the office of the Administrative Official named in item 12 on the Face Page of the PHS 398 (rev. 5/2001) application form.

2. Administrative and National Policy Requirements

All NIH Grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part4.htm and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_part9.htm.

2.A. Cooperative Agreement Terms and Conditions of Award

Not applicable.

3. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (<http://grants.nih.gov/grants/funding/2590/2590.htm>) and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues.

1. Scientific/Research Contacts:

GENERAL INQUIRIES regarding the scope and content of this program announcement should be directed to:

Ronald P. Abeles, Ph.D.
Special Assistant to the Director
Office of Behavioral and Social Sciences Research
National Institutes of Health
Gateway Building, Room 2C234, MSC 9205
7201 Wisconsin Avenue
Bethesda, MD 20892-9205
Telephone: 301-496-7859
Fax: 301-435-8779
E-mail: abeles@nih.gov

Direct inquiries regarding PROGRAMMATIC ISSUES, including questions of research areas of particular interest to and of possible funding mechanisms in addition to R01s at each IC, to the staff of the appropriate IC:

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2. Peer Review Contacts:

Not applicable.

3. Financial or Grants Management Contacts:

Ms. Judy Fox
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Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Human Embryonic Stem Cells (hESC):

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

Public Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov/>.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)



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